

§ 524.1376

(3) *Limitations.* Conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment. Cattle must not be slaughtered within 9 days following last treatment. Do not administer to dairy animals of breeding age. Do not treat animals before dipping or prior to exposure to heavy rain. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before using in severely debilitated animals.

[52 FR 10887, Apr. 6, 1987, as amended at 53 FR 7504, Mar. 9, 1988; 62 FR 61626, Nov. 19, 1997; 67 FR 78355, Dec. 24, 2002]

§ 524.1376 2-Mercaptobenzothiazole solution.

(a) *Specifications.* The drug contains 1.3 percent 2-mercaptobenzothiazole in a suitable solvent.

(b) *Sponsor.* See 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply twice daily to affected area.

(2) *Indications for use.* For dogs as an aid in the treatment of hot spots (moist dermatitis) and as first aid for scrapes and abrasions.

(3) *Limitations.* Clip hair from affected area before applying. If no improvement is seen within 1 week, consult a veterinarian.

[48 FR 15618, Apr. 12, 1983, as amended at 65 FR 50913, Aug. 22, 2000; 68 FR 33381, June 4, 2003]

§ 524.1443 Miconazole.

(a) *Specifications*—(1) Each gram of cream contains miconazole nitrate equivalent to 20 milligrams miconazole base.

(2) Each gram of lotion or spray contains miconazole nitrate equivalent to 1 percent miconazole base.

(b) *Sponsors.* See § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 000061 for use of cream, lotion, and spray;

(2) Nos. 054925 and 058829 for use of lotion and spray.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Apply once daily by rubbing into or spraying a light covering on the infected site and the immediate surrounding vicinity. Continue treatment for 2 to 4 weeks until infection is

21 CFR Ch. I (4–1–12 Edition)

completely eradicated as determined by appropriate laboratory examination.

(2) *Indications for use.* For topical treatment of infections caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 13542, Mar. 16, 2006]

§ 524.1445 Miconazole, polymixin B, and prednisolone suspension.

(a) *Specifications.* Each milliliter of suspension contains 23 milligrams (mg) miconazole nitrate, 0.5293 mg polymixin B sulfate, and 5 mg prednisolone acetate.

(b) *Sponsor.* See No. 012578 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Instill five drops in the ear canal twice daily for 7 consecutive days.

(2) *Indications for use.* For the treatment of canine otitis externa associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 4693, Jan. 29, 2010]

§ 524.1446 Milbemycin oxime solution.

(a) *Specifications.* Each tube contains 0.25 milliliter of a 0.1 percent solution of milbemycin oxime.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* One tube administered topically into each external ear canal.

(2) *Indications for use.* For the treatment of ear mite (*Otodectes cynotis*) infestations in cats and kittens 4 weeks of age and older. Effectiveness is maintained throughout the life cycle of the ear mite.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[65 FR 13905, Mar. 15, 2000, as amended at 66 FR 13849, Mar. 8, 2001]